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10/561,175	02/16/2006	Frederic Henot	37998-237505	1959

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EXAMINER	
WEN, SHARON X	
ART UNIT	PAPER NUMBER
1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,175	HENOT ET AL.	
	Examiner	Art Unit	
	SHARON WEN	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-17,22,23 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17,22,23 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant amendment, filed 12/17/2010, has been entered.

Claims 1-14, 18-21, 24-29 have been canceled.

Claims 15-17, 22-23, 30-32 are pending and currently under examination as they read on a pharmaceutical composition comprising a mixture of peptides having molecular weight of less than 10 kDa wherein grass allergen was the originally elected species. Applicant's election was made with traverse in response to election, filed 05/18/2007. Applicant's traverse was rebutted and the restriction required was made final in Office Action, mailed 07/25/2007. The examination as since been extended to tree allergen.

2. This Action will be in response to Applicant's Arguments/Remarks, filed 12/17/2010.

The rejections of record can be found in the previous Office Action, mailed 08/17/2010.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15-17, 22, 23, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new grounds of rejection are necessitated by Applicant's amendment, filed 12/17/2010.

Claims 15 and 31 recite the newly added limitation "the active ingredient". However there is insufficient antecedent basis for this limitation in the claim. It is unclear whether "the active ingredient" is referring to the mixture of peptides in the pharmaceutical composition or something else, especially given that the peptides are

hydrolyzed and presumably no longer retain its activity, e.g., enzymatice activity. Therefore, the claims are rendered indefinite by the recitation of "the active ingredient".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 15-17, 23, 30-32 stand rejected under 35 U.S.C. 102(e) as being anticipated by Focke et al. (U.S. Patent 7,244,431 B2, see entire document).

Applicant's argument has been carefully considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

> It is noted that Applicant elected grass allergen as the specific antigen in the claimed pharmaceutical composition. However, given the applicability of the prior art under 103(a) and the broadest reasonable interpretation of the claims, the following grounds of rejection are set forth.
>
> Focke et al. taught a pharmaceutical composition comprising a peptide (i.e., a birch tree allergen) having a molecular weight (MW) of less than 10 KDa wherein the peptide is a fragment of a protein (see, e.g., claim 1 and column 2, lines 62-67). It is noted the prior art peptide recited in claim 1 would have a MW of less than 10 kDa, given that it is 8 to 50 amino acids in length and that an amino acid has the average MW of 135 dalton. Therefore the peptide taught by the prior art inherently weighs less than 10 KDa. Furthermore, the prior art taught the amount of the peptide in the pharmaceutical composition to be in the range of 0.001-1000 ug and 1-100 ug (see, e.g., column 3, lines 44-47). Lastly, the prior art taught the pharmaceutical composition to be formulated for sublingual, oral or nasal administration which reads on buccal and enteric administration as recited in the present claims, under the broadest reasonable interpretation (see paragraph bridging columns 3-4).

In response to Applicant's argument that Focke et al. did not teach the newly added limitation which require the claimed pharmaceutical composition to be formulated for enteric administration wherein the active ingredient is protected from absorption and/or degradation prior to entry into the intestine, it is noted that the newly added limitation does not add or change the structural characteristics of the composition. The specification provides the following description:

> "Enteric administration" is a method wherein the substance is in a pharmaceutical formulation which protects the active ingredient from absorption and/or degradation prior to entry into the intestine. Preferably absorption is effected in the ileum, duodenum or jejunum. In one preferred embodiment, the said pharmaceutical formulation can be a suppository. (paragraph [0026] of the published application).

The disclosure does not provide any structural limitation for the formulation and the claims do not specify any levels of protection from absorption/degradation; thus the claims read on any level of protection from absorption/degradation. Therefore, under the broadest reasonable interpretation, any composition comprising the peptides formulated for pharmaceutical use reads on the claims because even water or buffer can offer certain level of protection from absorption/degradation prior to entry into the intestine.

Applicant's argument has not been found convincing. Therefore the rejection of record is hereby maintained.

7. Claims 15-17, 23, 27-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanabe et al. (BBRC 1996, 223:492-495, cited on IDS).

Applicant's argument has been carefully considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

> It is noted that Applicant has elected grass allergen as the specific peptide. However, given Applicant argues that the claimed composition comprises a mixture of peptide not a specific peptide, the following rejection is set forth.
>
> Tanabe et al. taught a pharmaceutical composition comprising a mixture of hydrolyzed peptides of an antigenic structure which induces allergic reaction (see entire document, in particular, see Abstract and Introduction). The peptides have been hydrolyzed by chymotrypsin (see Materials and Methods on page 492)

> and have a MW of less than 10KDa (see Figure 1). The amount of the peptides is in the range of 1 to 100 ug (see Material and Methods, Inhibition of ELISA). The instant specification does not provide limiting definition for sublingual, buccal or enteric formulation, as such the pharmaceutical composition taught by Tanabe et al. meets the claims because the composition can be administered via sublingual, buccal or enteric route, thus qualifying it to be sublingual, buccal or enteric formulation.

Applicant's argument and Examiner's rebuttal are essentially same as above. Given that the disclosure does not provide any structural limitation for the formulation and the claims do not specify any levels of protection from absorption/degradation; thus the claims read on any level of protection from absorption/degradation. Therefore, under the broadest reasonable interpretation, any composition comprising the peptides formulated for pharmaceutical use reads on the claims because even water or buffer can offer certain level of protection from absorption/degradation prior to entry into the intestine.

Applicant's argument has not been found convincing. Therefore the rejection of record is hereby maintained.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 15-17, 22, 23 and 27-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Focke et al. (U.S. Patent 7,244,431) and Marx (U.S. Patent 5,898,037, reference of record).

Applicant's argument has been carefully considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

> The teaching of Focke et al. has been discussed supra (see above).
> The only differences between Focke et al. and the present claims are 1) Focke did not explicitly teach grass allergen as the specific antigen in the claimed

pharmaceutical composition and 2) Focke et al. did not teach adding nucleoside triphosphates in the pharmaceutical composition.

Regarding grass allergen, the following is noted:

Even though Focke did not explicitly teach grass allergen, Focke stated that "allergenic proteins that can be envisaged are e.g. the major grass pollen..." (see column 2, lines 31-32). Therefore, it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, upon reading Focke et al, to substitute grass allergen for birch allergen (a tree allergen) in an allergy vaccine preparation for the same purpose of treating allergic disorders.

Furthermore, it would be obvious to pick from a finite number of identified allergens to try as taught by Focke et al. because, with a reasonable expectation of success, a person of ordinary skill has good reason to pursue the known options (e.g. preparing a pharmaceutical composition comprising a peptide/allergen that is less than 10 KDa and known allergens such as grass allergen, tree allergen, etc.) within his or her technical grasp. This leads to the anticipated success of making a pharmaceutical composition comprising a grass allergen that is less than 10 KDa. It is likely the product not of innovation but of ordinary skill and common sense.

Regarding nucleoside triphosphates, the following is noted:

Nucleoside triphosphates, such as ATP, were well-known adjuvants in a pharmaceutical composition formulated for treating allergic disorders as evidenced by Marx (see entire document, in particular, Detailed Description of Preferred Embodiments). Specifically, Marx teaches that ATP, a nucleoside triphosphate, is a preferred adjuvant in a composition suitable for treating allergic skin condition which reads on allergic reaction as a species reads on a genus (see column 5, lines 4-10 and lines 52-55).

Given the teaching by Focke on the pharmaceutical composition comprising tree or grass allergens for treating allergic reaction and the teaching by Marx on using ATP as an adjuvant for immunotherapy associated with allergic reaction, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a pharmaceutical composition comprising tree or grass allergens and nucleoside triphosphates such as ATP for immunotherapy associated with allergic reaction.

Furthermore, given the teaching by Focke et al. that the aim of the sublingual immunotherapy with grass allergens is to elicit protective antibody production (see column 1, lines 35-37), and that the teaching by Marx that ATP is a preferred adjuvant for treating allergic conditions (see column 5, lines 4-10 and lines 52-55), one of ordinary skill would have been motivated to add nucleoside triphosphates such as ATP in a pharmaceutical composition comprising grass allergen for sublingual immunotherapy.

Therefore, the invention, as a whole, was prima facie obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

In response to Applicant's argument that the present claims require hydrolyzed fragments of allergens, it is noted that such limitation is a product-by-process limitation wherein the allergen is obtainable by hydrolysis with chymotrypsin or any other protease". Since the reference taught a pharmaceutical composition comprising the one or more substances, i.e. birch tree allergens, the same substances obtainable by hydrolysis with chymotrypsin or any other protease would also be anticipated by the reference. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Applicant's argument regarding enteric formulation and Examiner's rebuttal are essentially the same as above. Given that the disclosure does not provide any structural limitation for the formulation and the claims do not specify any levels of protection from absorption/degradation; thus the claims read on any level of protection from absorption/degradation. Therefore, under the broadest reasonable interpretation, any composition comprising the peptides formulated for pharmaceutical use reads on the claims because even water or buffer can offer certain level of protection from absorption/degradation prior to entry into the intestine.

Applicant's argument has not been found convincing. Therefore the rejection of record is hereby maintained.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanabe et al. (BBRC 1996, 223:492-495, cited on IDS) and Marx (U.S. Patent 5,898,037, reference of record).

Applicant's argument has been carefully considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

The teaching by Tanabe et al. has been discussed above.

> Tanabe did not teach the pharmaceutical composition further comprising a nucleoside triphosphate. However, it would have been obvious to one of ordinary skill in the art to include a nucleoside triphophate such as ATP because ATP was well-known adjuvants in a pharmaceutical composition formulated for treating allergic disorders as taught by Marx (see entire document, in particular, Detailed Description of Preferred Embodiments). Specifically, Marx teaches that ATP, a nucleoside triphosphate, is a preferred adjuvant in a composition suitable for treating allergic skin condition which reads on allergic reaction as a species reads on a genus (see column 5, lines 4-10 and lines 52-55). Given that Tanabe taught a pharmaceutical composition that comprise a hydrolyzed peptides for treating allergic reaction (see page 495, first paragraph), one of ordinary skill in the art would have been motivated to include ATP in the composition in view of the clear teaching by Marx.
>
> Therefore, the invention, as a whole, was prima facie obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's argument and Examiner's rebuttal are essentially same as above. Given that the disclosure does not provide any structural limitation for the formulation and the claims do not specify any levels of protection from absorption/degradation; thus the claims read on any level of protection from absorption/degradation. Therefore, under the broadest reasonable interpretation, any composition comprising the peptides formulated for pharmaceutical use reads on the claims because even water or buffer can offer certain level of protection from absorption/degradation prior to entry into the intestine.

Applicant's argument has not been found convincing. Therefore the rejection of record is hereby maintained.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Huynh N. Phuong can be reached on (571)272-0846. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/
Primary Examiner, Art Unit 1644
March 14, 2011